REMARKS

Claims 1-4, 6-15, 17-23, and 25-27 are currently pending in this application. Claims 5, 16, and 24, previously withdrawn, are hereby canceled without prejudice to or disclaimer of the subject matter therein. Claims 26 and 27 are new. Each of the previously pending claims (1-4, 6-15, 17-23, and 25) stand rejected in the September 10, 2003, Office Action.

Support in the Application Regarding the Dilation Bladder

The Office Action alleges that "the dilation bladder being more rigid than the hyperdeformable [balloon] ... is not disclosed as far as applicant has cited on page 10 lines 2-25." In response, the undersigned submits that when the cited portions of the specification are read in light of the remainder of the application, there is ample support for the quoted claim language. For example, Figures 8-11, which are discussed at pages 10 and 11, make clear that the illustrated dilation bladder 84 may be less flexible than the hyderformable balloon 83 illustrated in these figures. As to Fig. 9, an expanded bladder 84 is illustrated and described in the accompanying text (see pg. 10 at 2-16) as being unable to reach the entire contoured surface of the vessel due to the bladder's rigidity or partial flexibility. Labeled uncontacted areas 90 highlight this material property of the dilation bladder 84. Conversely, the more flexible hyperdeformable balloon 83, when inflated, is able to contact these areas 90. This is shown in Fig. 11 and is described at page 11, lines 1-5 of the specification. Accordingly, the undersigned submits that adequate support in the application exists at least in these figures and the supporting text for the dilation bladder being more rigid (i.e., less flexible) than the hyderformable inflation balloon.

Objection to the Specification

The specification stands objected to as failing to allegedly provide proper antecedent basis for a balloon containing grooves. In response, the undersigned submits that the specification clearly teaches as page 5, lines 10-12, that the balloon may be internally notched or ribbed or otherwise specifically configured and that this teaching provides a basis for using the word grooved in the claims. *The American Heritage College Dictionary* supports this assertion as it defines ribbed as, inter alia, "to make with ridges or raised markings," and defines ridge as a "raised narrow strip." From these definitions it follows that between the ridges, raised markings or raised strips, furrows, channels or other lower areas (i.e. grooves) must exist.

Furthermore, the absence of the word grooved from the specification does not prevent its use in the claims. The MPEP recognizes this in section 1302.01 where it notes the exact terms found in the specification need not be used in the claims to satisfy 35 U.S.C. § 112 requirements. That section of the MPEP also points out that 37 C.F.R. § 121(e) requires only a substantial correspondence between the language of the claims and the language of the specification. *See* MPEP §1302.01. As a substantial correspondence exists between a balloon with grooves and one with internal ribs or notches, the undersigned submits that there is adequate support in the specification for the objected language.

Previously amended Figure 5 stands objected to as well. For the above reasons, the undersigned submits that the original specification also provides support for amended Figure 5 as well.

The Drawings Objection Under 37 C.F.R. 1.83(a)

The drawings are also objected to for allegedly failing to show a "a second balloon positioned between the dilation bladder and the first balloon." The undersigned submits that new Figure 16, which is Figure 13 redrawn to show a dilation bladder 165, a first balloon 163, orifices 160, and a second balloon 164, clearly shows the second balloon 164 inside the first balloon 163 and on top of the dilation bladder 165. Figure 16 does not represent new matter because support for it can at least be found in the specification's discussion of Figures 12-14, the figures themselves, and in as-filed claim 18, which notes that a second balloon may be positioned between the dilation bladder and the first balloon. Consequently, entry of Figure 16 is requested.

Information Disclosure Statement

An information disclosure statement was filed in this case on April 4, 2003, along with copies of the two references and the requisite fee. Proof of that filing is provided with a copy of the stamped postcard certifying receipt of these materials by the PTO. The undersigned requests further clarification as to the alleged 1.98(a)(2) violation described in the Office action. It is unclear by the language of the Office action exactly what the alleged shortcoming of the IDS filing was. Further clarification and verification, that the references cited thereon were considered and will be cited on the face of any granted patent, is requested.

35 U.S.C. § 112

Claims 7, 17, and 19 are rejected under 35 U.S.C. §112, second paragraph, as being allegedly vague and indefinite. The undersigned submits that these claims have been amended, therefore any alleged indefiniteness is moot.

35 U.S.C. § 102

Claims 1-4, 6, 8-12, 14-15, 19, 20-23, and 25 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Crocker et al. (U.S. Pat. No. 5,295,962). The undersigned submits that Crocker does not disclose or suggest an inflatable balloon wherein "the exterior surface of the first inflatable balloon ... [is] covered with a therapeutic when the first inflatable balloon is in an initial unexpanded state," as in claim 1. Crocker also fails to disclose or suggest "the exterior surface of the first inflatable balloon ... [is] covered with a therapeutic, the first inflatable balloon being impervious to the therapeutic," as in claim 12; "inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic," as in claim 20; and, "a grooved surface of the balloon, the grooved surface comprising ribs or notches," as in claim 26. For at least these reasons all of the pending claims are patentable over Crocker.

Crocker et al. (U.S. patent 5,295,962) is entitled "Drug Delivery and Dilation Catheter," and regards a drug delivery balloon disposed about an inflation balloon. *See* Abstract. Therapeutic is delivered in the Crocker device by forcing it from inside the balloon to outside the balloon. *See* Abstract; col. 7, lns. 43-67. This delivery occurs only after the delivery balloon is expanded at or near the target site. Thus, at no time in Crocker is therapeutic on the outside surface of the balloon prior to expanding the balloon. In each case, therapeutic from within the

balloon traverses a wall of an outer balloon to reach the balloon's surface. This is done with orifices in the balloon or making the balloon permeable to the drug. As to claims 1, 12, and 20, they substantially recite or have the effect of positioning therapeutic over an outer balloon before that balloon is expanded. As Crocker makes no similar suggestion, the undersigned submits that claims 1, 12, and 20, as well as their dependent claims, are all patentable over Crocker.

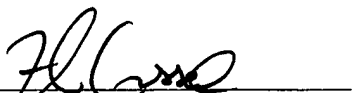
As to claim 26 and its dependant claim, Crocker fails to disclose or suggest a grooved balloon surface.

CONCLUSION

The undersigned requests further consideration and allowance of the pending claims. The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

Respectfully submitted,

Date: December 2, 2003



Fred T. Grasso
(Reg. No. 43,644)

KENYON & KENYON
1500 K Street, N.W., Suite 700
Washington, DC 20005
Tel: (202) 220-4200
Fax: (202) 220-4201

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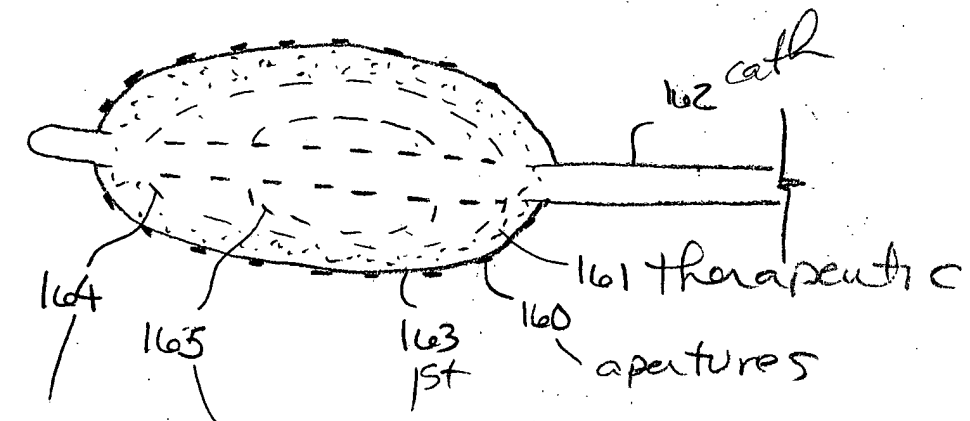

Fig. 16

Not ok